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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/686,997	10/12/2000	Olivier De Lacharriere	196726US0	5836

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EXAMINER

WILLIS, MICHAEL A

ART UNIT	PAPER NUMBER
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1617

DATE MAILED: 04/04/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application N .	Applicant(s)	
	09/686,997	DE LACHARRIERE ET AL.	
	Examiner	Art Unit	
	Michael A. Willis	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 March 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 12-14, 16-25 and 27-33 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 12-14, 16-25 and 27-33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 12 March 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicant's amendment of 12 March 2002 is entered. Claims 1-11, 15, 26, and 34-35 are cancelled. Claims 12 and 23 are amended. Claims 12-14, 16-25, and 27-33 are pending. Any previous rejections that are not restated in this Office Action are hereby withdrawn. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action. Applicant's request for reconsideration of the finality of the rejection of the last Office action is persuasive and, therefore, the finality of that action is withdrawn.

Drawings

2. The corrected or substitute drawings were received on 12 March 2002. These drawings are acceptable.

Response to Amendment

3. Claims 20, 21, 22, 31, 32, and 33 are rejected under 35 USC 112, second paragraph for reasons as stated in a previous Office Action. It is the position of the examiner that the standard for ascertaining the scope of claims to derivatives, i.e. sugar derivatives, arbutin derivatives, triazine derivatives, etc., is not provided.

4. The following new grounds of rejection are made:

Claim Rejections - 35 USC § 112

5. Claims 22 and 33 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims are rejected because the HMG-COA reductase inhibitor in these claims is not defined with any chemical or physical characteristic, but only by functional properties. A claim to a material defined solely in terms of what it can do, or a property thereof, does not particularly point out the claimed invention. Thus, the scope is indefinite. See *ex parte Pulvari* (POBA 1966) 157 USPQ 169.

Claim Rejections - 35 USC § 102

6. Claims 12-14 and 16-21 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Grollier et al (US Pat. 5,670,487). Grollier discloses compositions for combating skin blemishes. The invention relates to cosmetic compositions for depigmenting the skin (see col. 1, lines 10-15; and claim 11). Example 2 is comprised of 1.5% cholesterol, a biological precursor of DHEA (see col. 10, lines 29-67). It is the position of the examiner that 1.5% cholesterol meets the limitation of "about 1%" of claim 18. The compositions disclosed by Grollier further comprise terephthalylidene dicamphor sulfonic acid, which meets the limitation of a benzylidenecamphor-based UVB screening agent (see col. 3, line 30 through col. 6, line 54; and col. 10, lines 49-50). Example 2 further comprises arbutin (see col. 10, line 48).

Art Unit: 1617

7. Claims 12-14 and 16-22 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Ribier et al (US Pat. 5,607,692). Ribier discloses depigmenting compositions and methods (see col. 1, lines 9-20; and claim 15). The compositions comprise vesicles comprised of cholesterol (see col. 4, lines 23-67). The total weight of the vesicle in the compositions ranges from 1-90% (see col. 7, line 65 through col. 8, line 2). Additional components include sunscreen agents (see col. 6, lines 10-65). Keratolytic agents to be included in the composition include alpha-hydroxy acids (see col. 7, lines 1-5). Additional active agents include kojic acid and hydroquinone (see col. 7, lines 13-30). Example 1 includes cholesterol, kojic acid, and octanoylsalicylic acid (see col. 9, lines 25-50).

8. Claims 23-25, 27-30, and 33 are rejected under 35 USC 102(b) as being clearly anticipated by Diaz et al (US Pat. 5,942,531). Diaz discloses promotion of pigmentation of the hair or nails by administering topical compositions (see abstract; and col. 2, lines 35-40). Composition (n) comprises cholesterol and a "compound of formula (3)" which is disclosed as a retinoid (see col. 15, lines 20-30; and col. 2, line 60 through col. 4, line 15). It is the position of the examiner that the amount of .475% of cholesterol in example (n) is within the limitation of about 1%.

Claim Rejections - 35 USC § 103

9. Claims 12-14 and 16-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ribier et al (US Pat. 5,607,692). Ribier teaches depigmenting

Art Unit: 1617

compositions and methods (see col. 1, lines 9-20; and claim 15). The compositions comprise vesicles of cholesterol (see col. 4, lines 23-67). The total weight of the vesicles in the compositions ranges from 1-90% (see col. 7, line 65 through col. 8, line 2). Additional components include sunscreen agents (see col. 6, lines 10-65).

Keratolytic agents to be included in the composition include alpha-hydroxy acids (see col. 7, lines 1-5). Additional active agents include kojic acid and hydroquinone (see col. 7, lines 13-30). Example 1 includes cholesterol, kojic acid, and octanoylsalicylic acid (see col. 9, lines 25-50). The reference lacks disclosed examples of the full scope of the teachings, including weight percentages.

10. While the reference lacks disclosed examples encompassing all of the taught components, Ribier clearly teaches the advantages of using the cholesterol vesicles as the delivery vehicle for active agents depigmenting the skin (see col. 2, lines 10-50). With respect to weight percentages, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *In re Aller*, 220 F.2d 454, 105 USPQ 233, 235 (CCPA 1955).

11. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the compositions and methods of Ribier by the use of the full range of components taught by Ribier in order to benefit from the improved delivery of active agents via cholesterol vesicles as taught by Ribier.

12. Claims 23-25, and 27-33 are rejected under 35 USC 102(b) as being unpatentable over Diaz et al (US Pat. 5,942,531). Diaz teaches promotion of pigmentation of the hair or nails by administering topical compositions (see abstract; and col. 2, lines 35-40). Composition (n) comprises cholesterol and a "compound of formula (3)" which is disclosed as a retinoid (see col. 15, lines 20-30; and col. 2, line 60 through col. 4, line 15). Diaz teaches the additional use of active agents such as ascorbic acid (see col. 10, lines 25-28), and plant extracts (see col. 10, lines 40-42). It is noted that example (d) is a cosmetic sunscreen comprising benzylidenecamphor (see col. 12, lines 53-67). The reference lacks disclosed examples of the full scope of the teachings, including weight percentages.

13. While the reference lacks disclosed examples encompassing all of the taught components, Diaz clearly teaches the use of cholesterol in compositions with retinoids (see example (n), see also col. 8, lines 18-28). With respect to weight percentages, differences in concentration will not support the patentability of subject matter encompassed by the prior art unless there is evidence indicating such concentration is critical. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. *In re Aller*, 220 F.2d 454, 105 USPQ 233, 235 (CCPA 1955).

14. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the compositions and methods of Diaz by the full

Art Unit: 1617

range of components taught by Diaz in order to benefit from the improved administration of components taught by Diaz.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael A. Willis whose telephone number is (703) 305-1679. The examiner can normally be reached on Mon. to Fri. from 9 a.m. to 5:30 p.m.

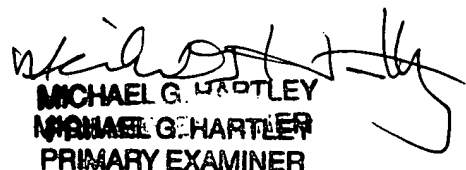
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Minna Moezie can be reached on (703) 308-4612. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.



Michael A. Willis
Examiner
Art Unit 1617

March 29, 2002



MICHAEL G. HARTLEY
MICHAEL G. HARTLEY
PRIMARY EXAMINER